



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Importer of Controlled Substances Registration: Alkermes Gainesville LLC

ACTION: Notice of registration.

SUMMARY: Alkermes Gainesville LLC applied to be registered as an importer of a basic class of controlled substance. The DEA grants Alkermes Gainesville LLC registration as an importer of this controlled substance.

SUPPLEMENTARY INFORMATION:

By notice dated June 10, 2014, and published in the *Federal Register* on June 17, 2014, 79 FR 34551, Alkermes Gainesville LLC, 1300 Gould Drive, Gainesville, Georgia 30504, applied to be registered as an importer of a certain basic class of controlled substance. No comments or objections were submitted for this notice.

The Drug Enforcement Administration (DEA) has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of Alkermes Gainesville LLC to import the basic class of controlled substance is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above-named company is granted registration as an importer of Noroxymorphone (9668), a basic class of controlled substance listed in schedule II.

The company plans to import the above listed controlled substance for analytical research and testing.

The import of the above listed basic class of controlled substance would be granted only for analytical testing and clinical testing. This authorization does not extend to the import of a finished FDA approved or non-approved dosage form for commercial distribution in the United States.

Dated: October 1, 2014.

Joseph T. Rannazzisi,
Deputy Assistant Administrator.

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